



December 3, 2018

Monet Vela  
Office of Environmental Health Hazard Assessment  
P. O. Box 4010, MS 23 11F  
Sacramento, California 95812-4010  
Telephone: 916-323-2517  
Fax: 916-323-2610  
E-mail: [monet.vela@oehha.ca.gov](mailto:monet.vela@oehha.ca.gov)

**Re.: Comments on Proposed Amendment to Sections 25821(a) and (c)**

Dear Ms. Vela:

The Frozen Potato Products Institute (FPPI) is pleased to submit these comments to the Office of Environmental Health and Hazard Assessment (OEHHA) regarding its Notice of Proposed Rulemaking to Article 8 of Title 27 of the California Code of Regulations pursuant to the Safe Drinking Water and Toxic Enforcement Act ("Proposition 65"). <sup>1/</sup> FPPI is the national trade association representing the producers and processors of frozen potato products, committed to representing their specific interests. The frozen potato products industry is committed to producing safe, wholesome, and nutritious products that consumers enjoy. Since acrylamide was discovered in foods about a decade ago, FPPI has made significant strides in better understanding acrylamide formation, developing effective acrylamide mitigation strategies, and educating Member Companies as well as end-users—both customers and consumers—about meaningful and practical acrylamide-reduction strategies.

FPPI is concerned the proposed amendments could have impacts that are contrary to the stated objectives of providing "clarification concerning the appropriate methods for calculating those exposures that require a warning and does not cause any significant economic impact on private persons or businesses." <sup>2/</sup> If adopted, the proposed changes would overrule the 2015 court decision in *Environmental Law Foundation v Beechnut Nutrition Corp* on how to determine the daily intake of listed chemicals as causing reproductive toxicity. The changes could impose additional testing requirements on the industry and could create a more rigid standard for

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<sup>1/</sup> October 5 (2018) Proposed Amendment to Sections 25821(a) and (c) Level of Exposure to Chemicals Causing Reproductive Toxicity: Calculating Intake by the Average Consumer of a Product (<https://oehha.ca.gov/proposition-65/cmr/proposed-amendment-sections-25821a-and-c-level-exposure-chemicals-causing>); Proposition 65 - Safe Drinking Water and Toxic Enforcement Act of 1986. (<http://www.oehha.org/prop65/law/P65law72003.html>).

<sup>2/</sup> Initial Statement of Reasons, Proposed Amendment to Title 27, California Code of Regulations Sections 25821(a) and (c) (<https://oehha.ca.gov/media/downloads/cmr/isor25821100518.pdf>).

companies to establish the dietary exposure of listed chemicals falls within a safe harbor under the Proposition 65.

The proposed amendments also present unique challenges for FPPI members. While the amendments only relate to reproductive toxicants, not the carcinogens, given the similar wordings of the regulations on the reproductive toxicants and carcinogens, we are concerned the private litigants will argue the same rationale also apply to the carcinogens once the proposal is adopted. FPPI is concerned the proposed amendments could potentially lead to more frivolous “shake-down” lawsuits, which will further dilute the quality of Proposition 65 warning.

Further, acrylamide is mainly formed during the final cooking step, manufacturers and producers of frozen potato products have very limited control over its formation. By essentially requiring each manufacturing facility to conduct its own testing for listed chemical, OEHHA’s proposed amendments could impose on every frozen potato manufacturers doing business in California with the significant, yet unnecessary, extra testing cost. The amendments could also have the unintended consequence of discouraging individual companies from collaborating with trade associations to develop industry data based on products sourced from multiple manufacturers and multiple facilities.

As discussed in more detail below, FPPI respectfully submits that OEHHA should withdraw the proposed amendments.

### **Proposed Amendment to Sections 25821(a)**

The proposed action would amend Title 27, California Code of Regulations section 25821(a) to prohibit the industry from continuing to use the average concentration of listed chemical from different manufacturers or facilities to assess Proposition 65 compliance, a practice recognized by the court in the 2015 *Beechnut* decision. If the amendments are adopted, the industry can only use data collected from a single manufacturing facility and each facility may need to conduct their own testing.

According to OEHHA’s Initial Statement of Reasons (ISOR), the agency noted that the amounts of listed chemicals in food products can vary significantly based on when and where the food was grown, processed, or packaged. As such, calculations of the concentration of a chemical in a food product for purposes of determining whether a warning is required should reflect an exposure that a consumer might reasonably receive from a product purchased at a specific time and place in California. OEHHA reasoned that if the concentration of a listed reproductive toxicant is high in one sample and low in another sample taken from a different location, averaging those concentrations could produce exposure estimates that bear little resemblance to the actual exposure an individual would experience from consumption of a certain product. Accordingly, OEHHA proposed amendments so it would not allow the use of average concentrations of the chemical in food products from different manufacturers or producers or from products manufactured in different facilities.

FPPI agrees with OEHHA that the concentration of a given chemical in food products could vary significantly based on when and where the food was grown, processed or packaged. And for this very reason, FPPI believes that data points for dietary exposure assessment should not be limited to a specific manufacturing facility. The current practice of determining average concentration of chemicals in products from different manufacturers and facilities ensures the results are representative of the products that are available to Californian residents. The proposed amendment, on the other hand, would force the industry to collect data from each facility that is producing products. These data points, on their own, are not representative of what an average Californian consumer would be exposed to when consuming a certain product.

This is especially the case when the data are collected for the same manufacturer from different manufacturing facilities. FPPI members routinely source the same branded products from different manufacturing facilities based on the production volume and manufacturing availability. In the marketplace, consumers view these food products interchangeably. Common sense also dictates that a purchase decision for food is often not made simply based on the location of a specific manufacturing facility. It is therefore arbitrary for OEHHA to make that distinction without considering the industry norm or the market reality.

#### **Proposed Amendment to Sections 25821(c)**

The proposed action would modify Section 25821(c)(2) to clarify that the reasonably anticipated rate of intake or exposure from a consumer product to a chemical listed as causing reproductive toxicity "is calculated as the arithmetic mean of the rate of intake or exposure for users of the product." It would essentially prohibit the industry from using the geometric means of food intake, which are often smaller than the arithmetic means.

In its ISOR, OEHHA noted that some consumers may use or consume a relatively large amount of a product, while other consumers may use the product in much smaller amounts. The existing regulation is silent about whether an average consumer's intake is to be characterized by the geometric mean, the median level, some other percentile, or the arithmetic mean. OEHHA reasoned that, because Proposition 65 is intended to warn Californians, of significant exposure to listed chemicals, a determination of the exposures to a chemical in a food or consumer product should be based on the full range of exposures experienced by Californians. OEHHA concluded that the arithmetic mean is the most appropriate way of measuring the intake because it accounts for consumption levels at both the low and the high end of the range, weighing the intake of each consumer equally.

FPPI agrees that consumer behavior necessarily varies and the anticipated rate of exposure for average users was adopted originally to avoid warnings based solely on occasional consumption at the highest levels. In the *Beechnut* case, during which the court ruled geometric means were allowed for intake assessment, the defendants' expert reasoned geometric means can help avoid the average intake data being "skewed" by a few outliers – consumers who ate a very high amount

and do not represent how an average Californian consumer would consume the products. <sup>3/</sup> The court sided with the defendants and accepted the use of geometric means.

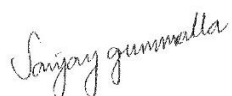
OEHHA's proposal would overturn this important finding in the *Beechnut* case, which the industry has been relying on since 2015. FPPI respectfully submits that this interpretation is also inconsistent with OEHHA's own regulation that requires the level of exposure be calculated using "the reasonably anticipated rate of intake or exposure for average users of the consumer product..." <sup>4/</sup> Treating the few very high intake data points as equal with the other data points will not yield the reasonably anticipated rate of intake of exposure for average users. This could potentially lead to the proliferation of unnecessary warnings in the marketplace when the dominant proportion of consumer intake does not warrant the warning, and further dilute the quality of Proposition 65 warnings. FPPI is also concerned that private litigants, with the ability of using the arithmetic means that are often higher than the geometric means, could be emboldened to file more "shake-down" lawsuits.

## **Conclusion**

FPPI applauds OEHHA's efforts in providing clarification concerning the appropriate methods for calculating dietary exposure for Proposition 65 assessment purpose. However, as discussed above, FPPI is concerned the proposed amendments, by overturning the court holdings in the *Beechnut* case, would impose significant burden on the industry with generating more unnecessary testing data. Requiring the use of arithmetic means in assessing dietary intake, as opposed to geometric means, is inconsistent with the existing regulation and could also unleash a new frontier for "shake-down" lawsuits. Therefore, FPPI respectfully submits that OEHHA should withdraw the proposed amendments.

FPPI thanks OEHHA for taking into consideration the comments and also generally supports the California Chamber of Commerce's submission.

Respectfully submitted,



Sanjay Gummalla, Ph.D.  
Executive Director  
Frozen Potato Products Institute

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<sup>3/</sup> *Environmental Law Foundation v Beechnut Nutrition Corp. et al.*, (2015) 235 Cal.App.4<sup>th</sup> 307.  
<sup>4/</sup> See 27 CCR Section 25821 (c)(2)